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Sharing benefits in international health research

Research-capacity building as an example of an indirect collective benefit

Annette Schulz-Baldes, Effy Vayena & Nikola Biller-Andorno

Over the past decade, clinical investigators and sponsors have shown increased interest in conducting clinical trials and other health-related research in resource-poor settings, notably Asia, Africa and South America. This move to poorer countries can bring many benefits: personnel costs are lower, and it is easier to recruit participants and to implement placebo-controlled trials that produce less ambiguous data, which might reduce the time it takes to approve a new drug. For the people in these areas, participating in clinical trials or basic research is often beneficial because it can give them an otherwise rare opportunity to access medical care (Ballantyne, 2005).

However, such research does not always address local health needs. Research participants are sometimes provided with medical care that is below the standards of developed countries, and drugs or therapies are not always made available to participants and their communities once they have been authorized for sale in North America or Europe. Although such research usually involves some benefits for participants and their communities, these benefits can still be unfair when compared with the benefits that sponsors and future patients in wealthier countries gain, or when the benefits do not outweigh the risks assumed by the participants and involved communities. In such cases, the research is exploitative.

It has been claimed that, in order to reduce exploitation in international health research, sponsors should provide 'fair' benefits to participants and their communities (Participants, 2002, 2004). Although

there has been much debate about what constitutes 'fair' research benefits, the related practical questions have received less attention. What is the range of possible benefits? Can they be distinguished in ethical terms? What concrete measures can be used to implement them in an ethically defensible way? In this article, we discuss advantages and challenges in the implementation of what we call 'indirect collective' research benefits in resource-poor settings, using the example of research-capacity building.

Exploitative transactions are defined by an unfair distribution of risks and benefits among the parties involved (Wertheimer, 1996). In the context of international health research, this can mean two things: study participants in resource-poor settings assume the risks of research, sometimes for little individual benefit, whereas patients in wealthier countries primarily benefit from the results; or sponsors do not provide research participants and communities with a fair share of the benefits or profits after successful completion of a study. Owing to restricted healthcare services, limited education, cultural differences and often fragmentary or inefficient research regulations, there is a particular risk of exploitation when sponsors or

investigators from wealthier countries conduct research in resource-poor settings (Macklin, 2004).

Within the global community, an unfair distribution of risks can be addressed by limiting research to studies that respond to the health needs of the community (CIOMS, 2002). However, reaching a fair distribution of research benefits between sponsors, study participants and their communities within the scope of a research project is more complex, and difficult to translate into practice. Although collective research benefits—such as reasonable availability of a new intervention—have always been controversial, what we refer to as indirect collective research benefits pose some particular conceptual and practical challenges.

A survey of the relevant literature and regulations for externally sponsored research in resource-poor settings reveals a recent change in what is considered a research benefit. Previously, the ethical acceptability of conducting research in poorer countries was primarily framed in terms of its responsiveness to the health needs and the priorities of the population or community involved (CIOMS, 2002). This, it was argued, not only justified selecting the study population solely on epidemiological grounds and in accordance with local or regional priorities, but also required that a proven intervention be made available to participants and the community after the study, and at reasonable costs. Indeed, most of the previous debates on research benefits revolved around the concept of reasonable availability (Crouch & Arras, 1998; Glantz *et al*,

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1998) and the standards of care provided to participants during a study (Macklin, 2004; Wendler *et al.*, 2004). Current international guidelines and recommendations on clinical research in developing countries emphasize the same points (WHO, 2000; CIOMS, 2002; WMA, 2002).

However, the main focus on 'reasonable availability' was criticized by an international working group convened in 2001 by the US National Institutes of Health (Bethesda, MD, USA) and the University of Malawi (Blantyre, Malawi) for being both too narrow and conceptually misleading (Participants, 2002, 2004). Instead, the group proposed a broader framework of 'fair benefits' to include not only medical treatment of participants during the study and availability of the proven intervention afterwards, but also collateral health services, public-health measures, employment and economic activity, capacity development and financial rewards.

The argument in favour of expanding the range of possible research benefits was that making an intervention reasonably available after the successful completion of a study was not a sufficient safeguard against exploitation, for both empirical and conceptual reasons (Participants, 2002, 2004). Empirically, it was argued, much clinical or health-related research involving humans did not aspire to or attain reasonable availability of a new therapy. Furthermore, binding agreements to make a new intervention reasonably available after national licensing were not always beneficial, as a less-expensive or more effective and equally expensive therapy might have been developed and approved in the meantime. Finally, communities could still be exploited even if the new intervention was made reasonably available—for example, when a new drug subsequently created large financial profits.

Conceptually, as the argument went, the focus on reasonable availability missed the key ethical issue in exploitation. According to Alan Wertheimer's concept of exploitation (Wertheimer, 1996), transactions are exploitative because they do not achieve fairness among interacting parties, not because they fail to provide a particular type of benefit to a particular party. Therefore, for the ethical conduct of a study, it is essential to provide participants

and communities with a fair level of research benefits—goods, services or money—not just the particular benefit of making the new intervention reasonably available (Participants, 2002, 2004).

According to this argument, the focus on reasonable availability alone represents unjustified paternalism. Rather than prescribing a particular benefit, communities themselves should be able to define their benefits according to their needs, values and priorities before engaging in a research project. For both empirical and conceptual reasons, the international working group concluded that the prevailing understanding of research benefits not only failed to prevent or reduce exploitation, but also increased paternalism in relation to communities or populations living under extremely constrained socioeconomic conditions (Participants, 2002, 2004).

The distinction between individual and collective research benefits is important because it is not straightforward that individuals would want to assume the risks, burdens and inconveniences of research for collective benefits—particularly if these benefits are indirect

These arguments apply to research in resource-poor settings where circumstances entail important benefits for sponsors, and where not sharing them would exacerbate existing global injustices. However, the resulting list of fair benefits is broad and difficult to navigate. Are all fair benefits equivalent from an ethical perspective or are some of their characteristics morally relevant for their delineation and implementation? Moreover, although the fair-benefit framework expands the range of possible benefits, it provides little guidance on how to put them into practice.

Research benefits can be differentiated by several characteristics. For example, whether they are direct or indirect—that is, whether the benefit is integral for the conduct of research—whether they benefit individuals or the collective, whether they affect basic or non-basic goods, and whether they are potential or

guaranteed. These characteristics all influence the delineation of research benefits and help to assign responsibilities for their provision. However, the distinction between individual and collective benefits is particularly relevant for the implementation of research benefits.

Direct benefits usually affect individuals; for example, when research participants are provided with medical treatment during and after a study. Others—such as community access to medical care, the provision of health services or health-research infrastructure, capacity building or financial rewards—usually apply at a collective level, but can entail individual benefits in the long term. The distinction between individual and collective research benefits is important because it is not straightforward that individuals would want to assume the risks, burdens and inconveniences of research for collective benefits—particularly if these benefits are indirect, such as research-capacity building or financial rewards.

Indirect collective benefits are not controversial if they are provided in addition to direct individual or collective benefits, or if they balance collective burdens; for example, by committing scarce resources such as trained health personnel (Gbadegesin & Wendler, 2006). However, in some research—for example, epidemiological studies—there might be no direct benefits either to the individual or at the collective level. Furthermore, it seems unrealistic to evaluate collective benefits only with regard to their effects on individuals (Participants, 2004), because some—for example, research-capacity building—have long-term effects with vague and uncertain individual benefits. However, even if indirect collective research benefits do not balance collective risks or burdens and are of uncertain benefit to the individual, they can be ethically defensible when certain requirements are met. This includes ensuring that the individual rights of research participants are protected, the individual risk-benefit ratio is favourable or the net individual risks are negligible, individual participants are aware of the collective benefit scheme and agree with it, and the collective benefits have been defined and outweigh collective risks from the perspective of the community. We will now use the example of research-capacity building to illustrate how these requirements can be met in practice, and the numerous conceptual and practical difficulties involved in guaranteeing them.

Table 1 | Determining research benefits for study participants and/or communities involved in research

Consulting the community to negotiate research benefits	Steps and considerations
Which community?	Identify the community according to community characteristics Identify degree of community involvement in research Study the chosen community with regard to sociocultural structure and political/traditional leadership
Which community representatives?	Identify legitimate representatives of the community, and do not reinforce existing inequitable structures and relationships, such as gender inequities
How to negotiate?	Provide information about the research Assess risks, burdens and benefits for individual participants, the community and sponsors Provide information about previous benefit agreements Provide support for negotiations Recognize that benefit negotiations are dynamic
What comes next?	Make benefit agreements publicly available

Health research benefits communities by improving health, reducing health inequities and helping to develop sustainable communities (Lansang & Dennis, 2004). Yet research-capacity building is not usually an integral part of a study. However, if adequately implemented, research-capacity building can reduce the risk of exploitation in international health research. With a focus on implementation, two main questions arise: how can the above requirements for indirect collective research benefits be met in practice and how can research-capacity building then be implemented?

There are few papers on the practical aspects of community consultations in clinical research (Diallo *et al*, 2005; Dickert & Sugarman, 2005; Gbadegesin & Wendler, 2006) and benefit-sharing agreements in genetic research (Alvarez-Castillo & Feinholz, 2006; Schuklenk & Kleinsmidt, 2006). Moreover, to our knowledge, none of these publications have specifically investigated how research benefits in clinical or health-related studies should be negotiated. However, it is possible to extrapolate general steps for this procedure (Table 1), and, at the same time, reveal some of the unresolved conceptual and practical questions about community involvement in research.

Before any consultations or negotiations begin, the community, which is usually a group of people who are linked by social ties, and who share common perspectives and a geographical location (MacQueen *et al*, 2001), must be identified. At this stage it is important to distinguish between different types of community according to particular

characteristics; guidelines written for one community cannot be blindly applied to another (Weijer & Emanuel, 2000). As the example of so-called indigenous communities illustrates, it can be difficult to decide who can claim community membership and on what grounds (Schuklenk & Kleinsmidt, 2006).

The next step is to identify the level of community involvement in the research. Usually, the benefits concern only those who actually participate, and who bear the risks and burdens. However, involvement as a group—for example, by using the community's resources, focusing on the community's customs, traditions and practices, or concentrating on a health feature that is characteristic of the community—makes the claim for research benefits even more poignant. Therefore, the degree of community involvement should be determined before negotiating possible benefits.

...if adequately implemented, research-capacity building can reduce the risk of exploitation in international health research

After the community and its involvement have been identified, legitimate representatives should be identified by studying the sociocultural structure, political and/or traditional leadership (Diallo *et al*, 2005). Such studies require support from the community itself, assistance from anthropologists, ethnologists, sociologists or political scientists, and take time; it can be difficult to determine who speaks for the community. This process must also recognize potential oppression within the community; the

choice of representatives should not reinforce existing inequitable structures and relationships, such as gender inequities (Alvarez-Castillo & Feinholz, 2006).

As soon as negotiations begin, information about the research must be provided, including the basic elements of informed consent, which comprise the purpose of the research, potential benefits and risks to participants and the community, procedures for subject recruitment, and exclusion and inclusion criteria (Diallo *et al*, 2005). Actual benefit negotiations are likely to face a number of difficulties. First is the complex task of assessing the risks, burdens and benefits for individuals, the community and sponsors, in order to estimate a fair distribution of benefits (Gbadegesin & Wendler, 2006). At this stage, individual and community risks must be carefully distinguished. Second, when the risks are considered acceptable, community representatives must determine community priorities, values and needs in order to define the corresponding benefits. This might not be straightforward. Third, once the risks and benefits have been circumscribed, it can be difficult to determine the fairness of an agreement, even when compared with previous agreements (Participants, 2002, 2004). Fourth and finally, to assure procedural fairness, independent mediating bodies might be necessary to balance unequal bargaining positions.

Along the way, it must be recognized that benefit negotiations are dynamic. Earlier agreements might have to be changed according to the outcomes of the study. In cases of successive research projects, it is preferable that community consultation takes place continuously (Diallo *et al*, 2005). Making benefit agreements publicly available is also an

Table 2 | Aspects of implementing research capacity building as a research benefit in clinical or health-related research

Area of research capacity building	Goal	Type of benefit	Duration of benefit	
Research priority setting	Research responsive to health needs Practically relevant research	Collective	–	Long term
Research design	High-quality research Practically relevant research results	Individual, collective	Short term	Long term
Staff development and infrastructure	Efficient implementation of research	Researchers, collective	Short term	Long term
Scientific and ethical review	Good design and conduct of research Protection of research participants	Individual, collective	–	Long term
Publication and result communication	High research impact	Researchers, collective	–	Long term
Dissemination and advocacy	High research impact	Collective	–	Long term
Fundraising and grant writing	More and better research	Researchers, collective	Short term	Long term
Stewardship for research	More and better research More and better researchers	Researchers, collective	Short term	Long term
Research partnerships	Intellectual and material exchange	Researchers	Short term	Long term
Profit sharing	Financial gain	Researchers, collective	Short term	Long term

important contribution towards establishing a standard of fairness in international research (Participants, 2004).

These general steps for negotiating benefit agreements with communities already present numerous practical problems, and further procedural and conceptual questions exist. What are valid criteria for an informed community decision? How can community coercion or inducement be identified and prevented? What is the equivalent of participant withdrawal at the community level? How should benefit agreements be integrated into national health policy, particularly when they include the provision of healthcare or capacity building? As national authorities have the primary responsibility for population health, they should be involved in the negotiation and provision of indirect collective research benefits. But what if national authorities are corrupt or no legitimate community representation can be identified?

Nevertheless, once an indirect collective research benefit has been appropriately negotiated, individual rights deserve particular attention. Because of the conceptual and practical questions that surround the negotiations with communities, protecting the rights of the individual study participant remains a primary requirement for ethically defensible research. This implies, most importantly, a favourable individual risk–benefit ratio or negligible net risks for individual participants, and their explicit agreement with the collective benefit scheme as part of the consent procedure.

Provided these general requirements are met and a community has concluded that research-capacity building should be an indirect benefit for study participation, what are appropriate measures for its implementation in resource-poor settings? We now show how various facets of research-capacity building translate into benefits to the community and/or individuals (Table 2).

...once an indirect collective research benefit has been appropriately negotiated, individual rights deserve particular attention

It is well recognized that addressing local health needs is critical to improving health in resource-poor settings and thereby entails long-term benefits for communities (Lansang & Dennis, 2004). Therefore, assessment of local health needs and the informed setting of research priorities should be an integral part of research-capacity building (Global Forum for Health Research, 2004). As priority setting is a long-term and continuous process, creating research collaborations, and sharing knowledge and capabilities between sponsors and/or researchers from resource-rich and resource-poor settings, is well-suited to improve health in poorer countries (Global Forum for Health Research, 2002).

The next step towards practically relevant and high-quality research is to develop

a scientifically robust research project, which ultimately benefits both individual study participants and the community. However, researchers in resource-poor settings might not always be well trained in research methodology, design or data analysis. In international collaborative research, a protocol is frequently designed by a group in the sponsoring country and only implemented by local researchers. Although there are learning opportunities even in these cases, it is important that local researchers actively take part in the project design and receive training in research methodology in order to build long-term research capacity.

The feasibility of a research project is also determined by local capacity, funding and facilities. When resources are scarce, it is often necessary to simplify protocols, adapt equipment or use alternative techniques—provided that the scientific validity of the adapted method can be ensured (Harris, 2004). Furthermore, feasibility of a research project depends on its acceptance by the community and local authorities. Recent examples in human immunodeficiency virus (HIV) studies, such as the tenofovir (Viread ; Gilead Sciences, Martinsried, Germany) trial with commercial sex workers in Cambodia, show that research projects cannot be implemented without appropriate community involvement (Page-Shafer *et al.*, 2005). Research-capacity building should allow researchers to design a project that is scientifically robust and feasible, and acceptable to the community.

Considering the significant individual and collective effects of research on healthcare, it is also important that research-capacity building promotes staff development and improves working conditions in health research, on both an institutional and a political level. If a scientific career remains an unattractive option for many young people in resource-poor countries—owing to a lack of scientific tradition and institutional support, low wages, insufficient funding for research projects and non-transparent recruitment of research workers (Harris, 2004; Sitthi-Amorn & Somrngthong, 2000)—research cannot be implemented efficiently.

Although the establishment of local scientific and ethics review boards has progressed in resource-poor settings, concerns persist about the structure of these committees, their standard operations and the expertise of their members. Encouraging development and correct functioning of ethical review committees is one of the best ways to ensure that research will actually serve the needs of the community and protect individual study participants (WHO, 2000). Research-capacity building should include training about the ethical aspects of research, assistance in the establishment of review boards, and programmes for continued education of board members and scientists (Harris, 2004).

Publishing research results is a prerequisite not only for making an impact on clinical practices and policy making, but also for advancing scientific careers and obtaining future funding. However, it might be difficult for researchers from resource-poor settings to present their findings in international journals, or to establish esteemed local or regional journals. Lack of experience in presentation, scientific writing and the English language, as well as lack of an established culture to publish research results (Harris, 2004), can lead researchers from resource-poor settings to present their work at conferences, in regional and national databases or in reports to health ministries—all of which are largely invisible to the international scientific community (Sadana & Pang, 2003). Work might also remain unpublished for political reasons. Research-capacity building could therefore include training researchers in scientific writing (Harris, 2004), and local scientific journals could be promoted by

integrating them into online registers or by establishing partnerships between publishing organizations.

...as the example of research-capacity building shows, the concept is riddled with conceptual and practical questions...

Publicly accessible research results can lead to individual and collective benefits by informing professional practices and policy making; they should therefore be disseminated and advocated beyond the scientific community. However, dissemination might be difficult in countries where health policy-making is often based on opinion rather than evidence, and where public access to information might be limited. To enhance the impact of research, capacity building could include training in dissemination and advocacy of scientific results in communities and among health policy makers. In order to incorporate scientific evidence into policy making, researchers and health officials should establish regular communication and collaboration through workshops, consultancy and so forth. Well-informed public-health officials from resource-poor countries are also expected to have greater influence on political debates and decisions on global health governance (Sitthi-Amorn & Somrngthong, 2000).

Securing funds is necessary to sustain research projects that address local health needs. Researchers from resource-poor countries might have limited experience in preparing competitive grant proposals or might even be unaware of funding opportunities (Harris, 2004). Research-capacity building could therefore also provide support in effective fundraising and grant writing.

Many countries have established national medical or health research coordination bodies to guarantee transparent and accountable allocation of funds, quality of research and alignment of research funding with national research priorities to ensure that communities benefit. Despite the need for such transparency, similar bodies do not exist in many resource-poor countries (Sadana & Pang, 2003). Research-capacity building could therefore help to establish or advance national authorities to oversee and coordinate health research.

The successful conduction and implementation of research requires input from various scientific disciplines, the community, and the political and private sectors. To advance the quality of research, capacity building could promote networking and scientific partnerships at national and international levels (Sitthi-Amorn & Somrngthong, 2000), as well as intersectoral partnerships between researchers and the community, civil society organizations, national health authorities and the private sector.

In some cases, considerable financial profits are gained from research results, and sharing these or intellectual property rights can benefit local researchers and the community. However, scientists—just like communities—might be unprepared to negotiate such agreements. Research-capacity building could therefore help to develop innovative ways of fair profit sharing, as well as subsequent profit investment.

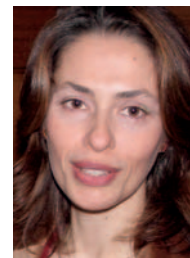
To conclude, providing indirect collective research benefits can be a genuine way to reduce exploitation in international research. However, as the example of research-capacity building shows, the concept is riddled with conceptual and practical questions, particularly regarding negotiations with communities. In the end, protecting the rights of individual participants remains a primary requirement for ethically defensible research in resource-poor countries or regions.

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This article reflects the personal opinion of the authors, and not necessarily the opinion of the World Health Organization.



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